



11-8-06

IFW

1646

Attorney Docket: 200512.00047

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Edward M. Medof and Lisa Kuttner-Kondo

Filed: 21 July 2006

Examiner: Not yet assigned

Serial No: 10/597,373

Art Unit: 1646

For: HYBRID AND CHIMERIC POLYPEPTIDES THAT REGULATE
ACTIVATION OF COMPLEMENT

Date: 7 November 2006

Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450


TRANSMITTAL

Transmitted herewith:

- 1) Information Disclosure Statement
- 2) PTO/SB/08a Form
- 3) Twentyseven (27) non patent literature documents
- 4) Acknowledgement of Receipt/Return Card

HAHN LOESER + PARKS LLP

By


John J. Cunniff
Reg. No. 42,451

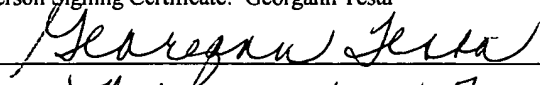
Certificate of Mailing By "Express Mail"

"Express Mail" Mailing Label Number: EV 612559915 US

Date of Deposit: November 7, 2006

I hereby certify that this correspondence is being deposited with the United States Postal Service "Express Mail Post Office To Addressee" service with sufficient postage on the date indicated above and is addressed to: Commissioner of Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Name of Person Signing Certificate: Georgann Testa

Signature: 

Date of Signing: November 7, 2006



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Edward M. Medof and Lisa Kuttner-Kondo

Filed: 21 July 2006

Examiner: Not yet assigned

Serial No: 10/597,373

Art Unit: 1646

For: HYBRID AND CHIMERIC POLYPEPTIDES THAT REGULATE
ACTIVATION OF COMPLEMENT

Date: 7 November 2006

Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Under 37 CFR §1.97

This Information Disclosure Statement is filed within three months of filing or before a first Office Action on the merits, and therefore, it is timely filed without payment of a fee. 37 CFR §1.97(b).

The filing of this Information Disclosure Statement shall not be construed as a representation that a search has been made (37 CFR §1.56(g)), an admission that the information cited is, or is considered to be, material to patentability or that no other material information exists.

The filing of this Information Disclosure Statement shall not be construed as an admission against interest in any manner. Notice of January 9, 1992, 1135 O.G. 13, at 25.

This Information Disclosure Statement is made to comply with the duty of candor imposed on all individuals associated with the filing or prosecution of this application, as defined by 37 CFR §1.56(c).

Twentyseven (27) non patent literature documents are listed on the attached six (6) sheets of Form PTO/SB/08A which is made a part hereof. A copy of each of the non patent literature documents are enclosed.

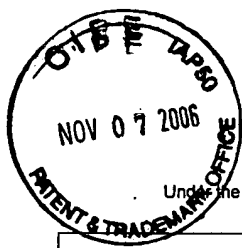
The foregoing Information Disclosure Statement is based upon the information known to the inventor or contained in the undersigned attorney's file as of the filing date of this statement and is inclusive of the best information known to each of the undersigned at that date. Prompt consideration of the Information Disclosure Statement and the references by the Examiner is earnestly requested.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "John J. Cunniff", with a stylized flourish at the end.

John J. Cunniff
Reg. No. 42,451

Hahn Loeser & Parks LLP
One GOJO Plaza
Suite 300
Akron, Ohio 44311-1076
330-864-5550
Atty. Docket: 200512.00047



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

PTO/SB/08a (08-03)

Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	10597373
Filing Date	2006-07-21
First Named Inventor	MEDOF, Edward
Art Unit	1646
Examiner Name	
Attorney Docket Number	200512.00047

U.S.PATENTS

Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

If you wish to add additional U.S. Patent citation information please click the Add button.

U.S.PATENT APPLICATION PUBLICATIONS

Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

If you wish to add additional U.S. Published Application citation information please click the Add button.

FOREIGN PATENT DOCUMENTS

Examiner Initial*	Cite No	Foreign Document Number ³	Country Code ² j	Kind Code ⁴	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T ⁵
	1							<input type="checkbox"/>

If you wish to add additional Foreign Patent Document citation information please click the Add button

NON-PATENT LITERATURE DOCUMENTS

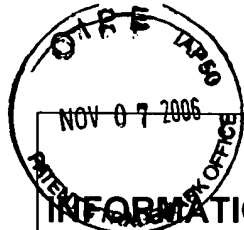
Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T ⁵



**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	10597373
Filing Date	2006-07-21
First Named Inventor	MEDOF, Edward
Art Unit	1646
Examiner Name	
Attorney Docket Number	200512.00047

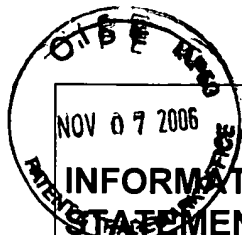
1	KUTTNER-KONDO and MEDOF; "Engineering of DAF-CR1 and DAF-MCP hybrid proteins for enhanced function;" Abstracts/Molecular Immunology; 2004; pgs. 264-265 (Abstract #138); Vol. 41	<input type="checkbox"/>
2	WEISMAN et al.; "Soluble human complement receptor type 1: in vivo inhibitor of complement suppressing post-ischemic myocardial inflammation and necrosis;" Science; July 13, 1990; pgs. 146-151; Vol. 249	<input type="checkbox"/>
3	KALLI et al.; "Mapping of the C3b-binding site of CR1 and construction of a (CR1)2-F(ab')2 chimeric complement inhibitor;" J. Exp. Med.; December 1991; pgs. 1451-1460; Vol. 174; The Rockefeller University Press	<input type="checkbox"/>
4	SONG et al.; "Complement receptor 2-mediated targeting of complement inhibitors to sites of complement activation;" The Journal of Clinical Investigation; June 2003; pgs. 1875-1885; Vol. 111, No. 12	<input type="checkbox"/>
5	FODOR et al.; "A novel bifunctional chimeric complement inhibitor that regulates C3 convertase and formation of the membrane attack complex;" The Journal of Immunology; 1995; pgs. 4135-4138; Vol. 155; The American Association of Immunologists	<input type="checkbox"/>
6	HIGGINS et al.; "A soluble chimeric complement inhibitory protein that possesses both decay-accelerating and factor I cofactor activities;" The Journal of Immunology; 1997; pgs. 2872-2881; Vol. 158; The American Association of Immunologists; U.S.A.	<input type="checkbox"/>
7	SALERNO et al.; "A soluble chimeric inhibitor of C3 and C5 convertases, complement activation blocker-2, prolongs graft survival in pig-to-rhesus monkey heart transplantation;" Xenotransplantation; 2002; pgs. 125-134; Vol. 9; United Kingdom	<input type="checkbox"/>
8	KROSHUS et al.; "A recombinant soluble chimeric complement inhibitor composed of human CD46 and CD55 reduces acute cardiac tissue injury in models of pig-to-human heart transplantation;" Transplantation; June 15, 2000; pgs. 2282-2289; Vol. 69, No. 11; Lippincott Williams & Wilkins, Inc.; U.S.A.	<input type="checkbox"/>
9	LI et al.; "Pharmacokinetics and safety of TP10, soluble complement receptor 1, in infants undergoing cardiopulmonary bypass;" American Heart Journal; January 2004; pgs. 173-180; Vol. 147; Elsevier Inc., U.S.A.	<input type="checkbox"/>
10	LAZAR et al.; "Soluble human complement receptor 1 limits ischemic damage in cardiac surgery patients at high risk requiring cardiopulmonary bypass;" Circulation; September 14, 2004; pgs. 11274-11279; Issue No. 0009-7322; Vol. 110 (Suppl II); The American Heart Association; Dallas, TX U.S.A.	<input type="checkbox"/>
11	SCHMID et al.; "TP20 is superior to TP10 in reducing ischemia/reperfusion injury in rat lung grafts;" Transplantation Proceedings; 2001; pgs. 948-949; Vol. 33; Elsevier Science Inc.; New York, NY U.S.A.	<input type="checkbox"/>



**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	10597373
Filing Date	2006-07-21
First Named Inventor	MEDOF, Edward
Art Unit	1646
Examiner Name	
Attorney Docket Number	200512.00047

12	ZIMMERMAN et al.; "Phase I trial of the recombinant soluble complement receptor 1 in acute lung injury and acute respiratory distress syndrome;" Crit Care Med; 2000; pgs. 3149-3154; Vol. 28, No. 9; Lippincott Williams & Wilkins; U.S.A.	<input type="checkbox"/>
13	COUSER et al.; "The effects of soluble recombinant complement receptor 1 on complement-mediated experimental glomerulonephritis;" Journal of the American Society of Nephrology; 1995; pgs. 1888-1894; Vol. 5, No. 11; The American Society of Nephrology; U.S.A.	<input type="checkbox"/>
14	KRYCH-GOLDBERG et al.; "Synergy between two active sites of human complement receptor type 1 (CD35) in complement regulation: implications for the structure of the classical pathway C3 convertase and generation of more potent inhibitors;" Journal of Immunology; 2005; pgs. 4528-4535; Vol. 175; The American Association of Immunologists, Inc. U.S.A.	<input type="checkbox"/>
15	HARRIS et al.; "Coupling complement regulators to immunoglobulin domains generates effective anti-complement reagents with extended half-life in vivo;" Clinical and Experimental Immunology; 2002; pgs. 198-207; Vol. 129; Blackwell Science	<input type="checkbox"/>
16	HARRIS et al.; "Generation of anti-complement "prodrugs": cleavable reagents for specific delivery of complement regulators to disease sites;" Journal of Biological Chemistry; September 19, 2003; pgs. 36068-36076; Vol. 278, No. 38; The American Society for Biochemistry and Molecular Biology, Inc.; U.S.A.	<input type="checkbox"/>
17	IWATA et al.; "Expression of a hybrid complement regulatory protein, membrane cofactor protein decay accelerating factor on Chinese Hamster Ovary. Comparison of its regulatory effect with those of decay accelerating factor and membrane cofactor protein;" Journal of Immunology; 1994; pgs. 3436-3444; Vol. 152; The American Association of Immunologists; U.S.A.	<input type="checkbox"/>
18	CHRISTIANSEN et al.; "Engineering of recombinant soluble CD46: an inhibitor of complement activation;" Immunology; 1996; pgs. 348-354; Vol. 87; Blackwell Science Ltd.	<input type="checkbox"/>
19	RINDER et al.; "Role of C3 cleavage in monocyte activation during extracorporeal circulation;" Circulation; August 3, 1999; pgs. 553-558; Vol. 100; American Heart Association, Inc.; Dallas, TX U.S.A.	<input type="checkbox"/>
20	SOUZA et al; "APT070 (Mirococept), a membrane-localised complement inhibitor, inhibits inflammatory responses that follow intestinal ischaemia and reperfusion injury;" British Journal of Pharmacology; 2005; pgs. 1027-1034; Vol. 145; Nature Publishing Group	<input type="checkbox"/>
21	LAM et al.; "The effect of soluble complement receptor type 1 on acute humoral xenograft rejection in hDAF-transgenic pig-to-primate life-supporting kidney xenografts;" Xenotransplantation; 2005; pgs. 20-29; Vol. 12; Singapore	<input type="checkbox"/>
22	HENRY et al.; "Complement activation is responsible for acute toxicities in rhesus monkeys treated with a phosphorothioate oligodeoxynucleotide;" International Immunopharmacology; 2002, pgs. 1657-1666; Elsevier Science B.V.	<input type="checkbox"/>



**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	10597373
Filing Date	2006-07-21
First Named Inventor	MEDOF, Edward
Art Unit	1646
Examiner Name	
Attorney Docket Number	200512.00047

23	VON DOBSCHUETZ et al.; "Soluble complement receptor 1 preserves endothelial barrier function and microcirculation in postischemic pancreatitis in the rat;" American Journal of Physiology - Gastrointestinal Liver Physiology; December 23, 2003; pgs. 791-796; Vol. 286; American Physiological Society; Bethesda, MD U.S.A.	<input type="checkbox"/>
24	YAZDANBAKHS, KARINA; "Development of complement therapeutics for inhibition of immune-mediated red cell destruction;" Transfusion; August 2005; pgs. 122S-129S; Vol. 45	<input type="checkbox"/>
25	XOMA Ltd.; "MLN01 and CAB-2 with Millennium Pharmaceuticals, Inc.;" Press Release; May 15, 2003; pg. 2; U.S.A.	<input type="checkbox"/>
26	BIOSPACE BEAT; "XOMA (XOMA) and Millennium Pharmaceuticals, Inc. (California) (MLNM) announce initiation of phase I clinical trial of MLN2222 - A.K.A. CAB-2 - a novel complement inhibitor;" Press Release; December 18, 2003; U.S.A.	<input type="checkbox"/>
27	AVANT IMMUNOTHERAPEUTICS, INC.; www.avantimmune.com/products/tp10.html and www.avantimmune.com/products/tp20.html	<input type="checkbox"/>

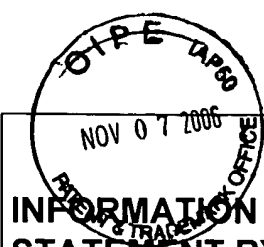
If you wish to add additional non-patent literature document citation information please click the Add button

EXAMINER SIGNATURE

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.



**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	10597373
Filing Date	2006-07-21
First Named Inventor	MEDOF, Edward
Art Unit	1646
Examiner Name	
Attorney Docket Number	200512.00047

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ None

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature		Date (YYYY-MM-DD)	2006-11-06
Name/Print	John J. Cuniff	Registration Number	42451

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**



Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.